

K 964178

Summary of Safety and Effectiveness

Encore Orthopedics®, Inc.
8900 Shoal Creek Blvd.
Building 300
Austin, TX 78757
512-795-8696

MAY -5 1997

Trade Name: Foundation® Press-Fit Hip Stem

Common Name: Press-fit hip stem

Classification Name: Hip joint metal/polymer semi-constrained prosthesis

Description: The proximal body is trapezoidal in cross-sectional geometry. The distal stem portion is conical in shape and has flutes to provide rotational stability. A coronal slot in the larger stems decreases implant stiffness.

The stem is available with and without a calcar collar and has a Morse type taper to receive modular heads. The neck/stem angle is 132°.

The Foundation® Press-Fit Hip Stem is fabricated from wrought/forged Ti-6Al-4V. The proximal body of the stem has a plasma sprayed surface to enhance press-fit fixation.

Intended Use: The Foundation® Press-Fit Hip Stem is intended for treatment of patients who are candidates for total hip arthroplasty because the natural femoral head and neck have been affected by osteoarthritis, inflammatory arthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis or femoral neck fracture, and revision arthroplasty where bone loss is minimal. It is intended to be used press-fit.

Comparable Features to Predicate Device(s): Features comparable to predicate devices include Ti-6Al-4V substrate, straight stem, symmetric, calcar collar, no collar, distal fluted stem, modular heads and distal coronal slot..

Test Results: Laboratory testing of the Morse type taper was conducted.